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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/734,671

12/12/2003

Seth A. Foerster

032,290-112

6289

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EXAMINER

ROY, ANURADHA

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/734,671	Applicant(s) FOERSTER ET AL.	
	Examiner Anuradha Roy	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/30/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Particularly, "a quantity of ultrasound-detectable bio-resorbable powder," is not disclosed in the specifications of the current application or of the parent applications; therefore, "a quantity of ultrasound-detectable bio-resorbable powder," is considered new matter and should be cancelled from the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Fisher (US Patent No. 6,350,244).

Regarding claims 46 & 47, Fisher discloses a ready to use assembly for delivering a biopsy marker mass (10), comprising a tube (12), said tube having an inner lumen (14) and being configured to be received by a biopsy guide cannula (24), a quantity of ultrasound-detectable bio-resorbable powder (16 & Column 3, lines 47-67 & Column 4, lines 1-11) disposed within the inner lumen of said tube. Additionally, Fisher discloses the assembly comprising a radiopaque material (Column 3, lines 35-36) disposed within said tube, which comprises a marker formed in a recognizable shape not naturally found within a patient's body (Column 3, lines 28-34).

In regards to claim 48, Fisher discloses a system for marking a biopsy site within a patient, comprising: a delivery tube (12) having a bore with a proximal portion and a distal portion (14, 13, & Column 14, line 64; Examiner notes, when a distal portion exists, it is inherent that a proximal end exists as well), a plunger (18) slidably disposed within said bore proximal portion, and a discharge end on said distal portion; and a quantity of ultrasound detectable bioresorbable powder disposed within said bore distal portion (Column 4, lines 64-65).

Additional Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirsch et al. (US Patent No. 5,395,319).

Regarding claim 49, Hirsch et al. discloses a delivery system for delivering marker material to a target site within a patient, comprising: an elongate member (12) having a distal end, a discharge port (14) in the distal end and an inner lumen extending therein to and in fluid communication with the discharge port in the distal end; a mass of solid particulate marker material (10) disposed within the inner lumen; and an ejector (24) which is advancable with and coupled to said elongate member and which is configured to eject particulate marker material from the discharge port in said distal end of said elongate member.

Response to Arguments

Applicant's arguments filed January 30, 2006 have been fully considered but they are not persuasive. Claims 46-48 are not entitled to the priority date of September 16, 1994. As stated above, "a quantity of ultrasound-detectable bio-resorbable powder," is not disclosed in the specifications of the current application or of the parent applications.

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therefore, "a quantity of ultrasound-detectable bio-resorbable powder," is considered new matter and its effective filing date is December 12, 2003. For these reasons, Applicant is required to cancel "a quantity of ultrasound-detectable bio-resorbable powder" or to direct the Examiner to a disclosure of the element in the current or parent applications.

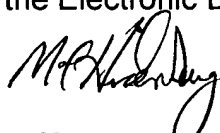
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~


MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
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